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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,626	03/09/2001	Leslie Lobel	62259/IPW/SHS	5559

7590

04/06/2004

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/804,626	Applicant(s) LOBEL ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 7, 16, 18 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7, 16, 18, and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED OFFICE ACTION

Applicant's amendment filed on 01 March 2004 is acknowledged and entered. Following the amendment, claims 32-42 and 44-47 are canceled, and claims 1, 2, 4, 7, 16, 25 and 26 are amended.

Currently, claims 1, 2, 4, 7, 16, 18, and 24-26 are pending, and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 7, 16, 18, and 24-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hsueh et al., US5,925,549, and McCoy et al., US5,270,181, for the reasons of record set forth in the last Office Action mailed on 05 December 2003, at pages 4-5.

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Applicants argument filed on 17 May 2000 has been fully considered, but is not deemed persuasive for reasons below.

At pages 5-6 of the response, the applicant argues that the cited references fail to support a prima facie case of obviousness because one of skill would not have had a reasonable expectation of success in combining the teaching of the two, that as McCoy teaches the benefits of a thioredoxin fusion protein for stabilization and solubilization of small polypeptides, such as polypeptides of 14, ..., and 223 amino acids in length as they are often poorly expressed in bacteria, and in contrast the polypeptide in the present invention has 336 amino acids, and that if McCoy had solved the problem for all bacterially expressed proteins, the art would have been expected to produce the claimed receptor during the 8 years following the McCoy patent. This argument is not persuasive because, while McCoy's system may facilitates the expression of "small" sized polypeptides such as that of 223 amino acids, it does not exclude "large" polypeptides such as that of 336 amino acids. Among McCoy's polypeptides demonstrated, the sizes vary from 14 amino acids to 223 amino acids in length, and the later is 1600% increase in size comparing to the one having 14 amino acids, whereas the polypeptide of 336 amino acids in the present invention is merely a 50% increase in size from 223 amino acids. Therefore, polypeptides of 223 amino acids and 336 amino acids are considered to be in the same size range. Further, the reference does not define "small" polypeptides. It is unclear how the "small" and "large" is defined, and where the line is drawn between "small" and "large". If McCoy's polypeptide of 223 amino acids is considered "small", is 250, 280 or 300 amino acids considered "large"? Furthermore, contrary to applicants argument, McCoy teaches that the invention is *not limited to any* specific type of heterologous peptide or protein, a wide variety of heterologous genes or gene fragments are useful in forming the fusion sequences for the invention, ... heterologous peptides or proteins can *include any* peptide or protein useful for human or veterinary therapy, diagnostic or research applications in any expression system (column 9, lines 8-19).

With respect to the argument in lack of progress in the field for 8 years, such is not an evidence for patent novelty or lack of obviousness. Applicants have not provided any additional fact or evidence to overcome the rejection.

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With respect to the argument in lack of a prima facie case of obviousness because of lack of a reasonable expectation of success from the combined teaching of the two references, it is not persuasive because McCoy has demonstrated the successful expression of *multiple* heterologous proteins (column 9, the third paragraph), which is a clear indication of *a reasonable expectation* of success in expressing any given peptide or protein (which is not equal to a complete certainty of success).

Conclusion:

No claim is allowed.

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Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in black ink, reading "Loraine Spector". The signature is written in a cursive style with a large, looping initial "L".

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/31/04